

BEFORE THE
OFFICE OF ADMINISTRATIVE HEARINGS
STATE OF CALIFORNIA

In the Matter of:

KAJ S.,

Claimant,

vs.

NORTH BAY REGIONAL CENTER,

Service Agency.

OAH No. N 2006100868

DECISION

Administrative Law Judge David L. Benjamin, State of California, Office of Administrative Hearings, heard this matter in Santa Rosa, California, on January 11, February 26, April 2, and May 11, 2007.

Nancy Ryan, Attorney at Law, represented the North Bay Regional Center (NBRC).

Claimant Kaj S. was represented by his mother and father, Alexandra K. and Jan S.

The matter was submitted on May 11, 2007.

ISSUE PRESENTED

Whether NBRC is obligated to reimburse claimant's parents for the cost of attending a two-day training conference on Relationship Development Intervention (RDI), an autism treatment program.

EVIDENTIARY RULING

NBRC's objection to the admission of claimant's Exhibit P is overruled. Exhibit P is admitted.

FACTUAL FINDINGS

1. Claimant is a 12-year-old NBRC consumer who has been diagnosed with autism. In September 2006, claimant's mother, Alexandra K., asked NBRC to pay for her

and her husband to attend a two-day conference in Los Angeles on RDI. On October 5, 2006, after a meeting of its Program Assessment and Review Team, NBRC sent Alexandra K. a Notice of Proposed Action, denying her request. The notice stated that NBRC was denying the request because NBRC does not fund unproven or experimental services, and it views RDI as unproven or experimental. Alexandra K. filed a Fair Hearing Request on October 18, 2006. Alexandra K. and Jan S. attended the RDI conference on November 3 and 4, 2006. They seek reimbursement for their conference registration (\$500), a DVD on RDI training (\$150), and an RDI workbook (\$25.99).

2. Claimant was diagnosed as autistic in October 2004, when he was 10 years old. He is eligible for regional center services under the Lanterman Act¹ by virtue of his diagnosis. Claimant was a regional center consumer because of cerebral palsy before he was diagnosed as autistic; his cerebral palsy has improved, however, and he is no longer eligible for regional center services due to that condition.

3. Claimant has impairments in communication skills, and impairments in social understanding and functioning, that are the “core deficits” associated with autism. NBRC’s psychologist, Suzanne Bordin, Ph.D., testified that an autistic child tries to control the world and does not respond to other people or changes in his environment. The child will use language to meet his own needs, but not to inquire into the needs of others. These impairments interfere with his ability to be a good family member, to do well in school, and to develop friendships.

Claimant’s Individual Program Plans (IPPs) have noted his impaired social and communication skills since at least October 2001. NBRC has funded various services and supports to address these impairments, including Lattice Social Skills classes. Over the past six years, claimant’s IPPs and IPP addenda have noted continual improvement in his social and communication skills; the July 2004 IPP addendum, for example, noted that claimant went to summer camp and “came home singing a camp song and sharing that he caught a fish, which is ‘a first’ for him.” But, despite improvement, serious impairments remain.

Claimant attends an ANOVA social skills class, where his therapist works with him on the “pragmatics” of social interaction. For the past year and one-half, he has also been attending an after-school class with a “social thinking” curriculum. Claimant’s public school district pays for the ANOVA class, and his parents are funding the social thinking class themselves.

4. RDI was developed by Steven Gutstein, Ph.D., director of The Connections Center in Houston, Texas. RDI is a proprietary program which Dr. Gutstein markets through The Connections Center. The Connections Center website describes RDI as “a parent-based clinical treatment for individuals with autism spectrum and other relationship-based disorders. [¶] It is the first systematic program designed to help children born with obstacles preventing them from attaining relationship competence.”

¹ Lanterman Developmental Disabilities Services Act, Welfare and Institutions Code section 4500 et seq.

RDI is aimed directly at autism's core deficits. The Connections Center website states:

The RDI™ Program provides a path for people on the Autism Spectrum to learn friendship, empathy and a love of sharing their world with others. Language comes alive when integrated with real emotion. People with Autism and Asperger's learn not only to tolerate, but to enjoy change, transition and going with the flow. It begins at the edge of each person's current capability and carefully teaches the skills needed for competence and fulfillment in a complex world.

If RDI's claim is true, that it allows persons with autism to "learn friendship, empathy and a love of sharing their world with others," then RDI treatment is revolutionary. As Dr. Bordin testified, these are the interactions that families treasure most, and the inability to develop such interactions is due to the core deficits of autism. Dr. Bordin states that, before RDI, no one promised such a result for an autistic child. Dr. Bordin testified that The Connection Center is reputable.

Parents who choose to follow the RDI program attend a four-day, personalized parent training course. Then, each month, the parents send four to 10 hours of videotape of their child to an RDI-certified consultant, who reviews the tapes and evaluates the parents' implementation of the program. The parents also attend two 12-hour RDI assessments per year. The estimated cost of the RDI program for one child is in the range of \$10,000 to \$25,000 per year.

5. NBRC's purchase of service policy states that NBRC "does not purchase unproven or experimental programs, interventions, services or equipment." The policy does not define the words "unproven" or "experimental." At hearing, Dr. Bordin testified that, to be proven, a service must be based on a valid, empirical study with comparison groups, controls, objective measurements, and observers who are "blind" to the treatment being administered. In essence, Dr. Bordin described credible studies based on randomized, controlled trials (RCTs).

Dr. Bordin acknowledged, however, that NBRC has purchased services and supports for children with autism that have not been established through RCTs. It funded a six-month trial of Applied Behavioral Analysis for a seven-year-old autistic child, and it funded the Lattice Social Skills classes for claimant, neither of which was supported by RCTs. NBRC takes various factors into account in determining whether to fund a service, including the availability of other interventions, evidence of efficacy, evidence of harm, and the desires of the family; if there is evidence of efficacy and no evidence of harm, NBRC considers new forms of treatment on an individual basis. In the case of RDI, Dr. Bordin testified, there is no evidence that it is harmful. However, she found it difficult to approve RDI given the "extravagance" of its claim and the absence of evidence to support its effectiveness.

6. The only study on the effectiveness of RDI is described in an undated manuscript by Dr. Gutstein entitled “Preliminary Evaluation of the Relationship Development Intervention Program.” The title page of the manuscript states that it was accepted for publication by the Journal of Autism and Developmental Disorders, but the evidence fails to establish that the manuscript was published.

The manuscript states that the study is based on Dr. Gutstein’s chart review of 31 children between the ages of two and 10, whose families came to The Connections Center for consultation between January 2001 and November 2002. The children were divided into two groups. One group consisted of 17 children whose parents followed the RDI program. The other group consisted of 14 children whose families did not pursue RDI. On average, the RDI group was one year younger than the non-RDI group, and the RDI group had a higher average IQ – 87 compared to 75 – than the non-RDI group. The RDI group had significantly more children with an initial diagnosis of Asperger’s syndrome, and the non-RDI group had significantly more children with a PDD NOS diagnosis (Pervasive Developmental Disorder – Not Otherwise Specified). To evaluate the progress of the two groups, Dr. Gutstein compared their improvement, or lack of improvement, based on their ADOS testing (Autistic Diagnostic Observation Schedule), and their educational placement at the end of the study period.

The manuscript reports that, based on their ADOS evaluations, 70 percent of the RDI children “improved at least one diagnostic category. Four children went from Autism to non-autism, five from Autism Spectrum to non-Autism, and three from Autism to Autism Spectrum. In contrast, not a single child in the non-RDI group improved [in his or her ADOS] diagnostic category.” With respect to educational placement, by the end of the study the majority of the children in the RDI group were attending regular education class without significant support, while “not a single child in the non-RDI group had moved from a special to a regular education setting and only a single child, who had previously attended regular classes, was enrolled in a regular education setting at the [conclusion of the study].”

In the manuscript, Dr. Gutstein notes limitations in the study that “forestall definitive conclusions”:

Results are based on examination of a small sample of relatively “high functioning” children. . . . The variety of measures used to evaluate cognitive functioning make a valid comparison impossible. Future studies should make sure that RDI and non-RDI groups are comparable . . . [O]lder children and Teenagers were not studied. Thus, the effects of age, cognitive and language functioning on treatment effectiveness are as yet untested. The current results were obtained using consultants from a single setting – the clinic where RDI was initially developed. . . . Finally, the retrospective nature of the study, precluding random assignment or matching procedures, opens up the possibility of a self-selection bias where important

variables led to parents choosing RDI vs. another intervention method.

Despite these limitations, the manuscript states that the study provides “early validation of the ability of RDI to impact . . . a core deficit of Autism.”

7. The Gutstein study does not provide a reliable indication of the effectiveness of RDI.

In addition to the problems noted in the manuscript itself, Dr. Bordin identified other flaws in the study. The RDI group was younger and had a significantly higher average IQ, the two most important factors in determining outcome for children with autism. While the average IQ of the RDI group was “remarkable” for autistic children, the average IQ of the non-RDI group indicated borderline intellectual functioning. In addition, most of the children in the RDI group carried a diagnosis – Asperger’s syndrome – which is not universally recognized as autism, and which is not associated with the same deficits as a diagnosis of PDD NOS. Dr. Bordin testified that the use of ADOS was inappropriate, as it is semi-objective and it is intended for diagnostic purposes, not as an instrument to measure progress.

Richard L. Kravitz, M.D., M.S.P.H., testified on claimant’s behalf. He is a professor of medicine at the University of California, Davis, and he is an expert in the design of research studies and the evaluation of clinical evidence. Dr. Kravitz acknowledged that the Gutstein study is “significantly flawed” because it was “not randomized, not blinded, and based on a small sample size.” Dr. Kravitz believes that the Gutstein study is “promising,” but that more research is needed.

8. In November 2005, the magazine Autism Spectrum Quarterly published an article by Dr. Gutstein which described the RDI program. The article is descriptive only; it offers no data to support the efficacy of RDI, other than references to the study described in Factual Finding 6. Articles published in Autism Spectrum Quarterly are not peer-reviewed.

Alexandra K. testified that Autism Spectrum Quarterly has an august advisory board. Claimant seems to argue that since Autism Spectrum Quarterly published Dr. Gutstein’s article, its advisory board supports the RDI program. Claimant’s argument – if indeed that it is his argument – is speculative. No evidence was offered to establish that the advisory board of Autism Spectrum Quarterly plays a role in the selection of articles for publication, that it approved the publication of Dr. Gutstein’s article for publication, or that it supports RDI.

9. Claimant’s parents are both physicians who have been trained in the principles of “evidence based medicine.” They contend that, under those principles, NBRC’s insistence upon RCTs is unreasonable. Evidence based medicine, Alexandra K. testified, “integrates best current research evidence with clinical and educational expertise and relevant stakeholder perspectives” to evaluate the effectiveness of a given treatment. Evidence based medicine recognizes that physicians make treatment recommendations on a wide range of

evidence of varying strength. Alexandra K. points to the clinical guidelines of the Royal College of Speech and Language Therapists, which assigns grades to the varying levels of evidence. At the top of scale – “Grade A” – is evidence obtained from RCTs; at the low end of the scale – “Grade C” – is evidence obtained from expert committee reports, or opinions and/or clinical experience from respected authorities. In between – “Grade B” – is evidence from well-conducted clinical studies, but not RCTs.

Alexandra K. testified that most treatment decisions, indeed the vast majority of treatment decisions, are not supported by RCTs. In addition, Alexandra K. stated, RCTs are appropriate for the evaluation of pharmaceuticals, where the evaluator and the subject are both blind to the treatment being offered; they are not appropriate, she stated, for behavioral interventions, where at least one person must be aware of the intervention that is being used.

Alexandra K. believes that the evidence supporting RDI falls somewhere between Grades C and B on the scale from the Royal College of Speech and Language Therapists, and that it is sufficient proof of RDI’s efficacy.

10. Alexandra K. testified that claimant’s physician recommended RDI; that the American Speech-Language-Hearing Association and the California Board of Behavioral Sciences award continuing education credit to members who attend an RDI conference; and that a Canadian company has developed an online program called “AutismPro” which identifies the full range of interventions available for autism, and it includes RDI in the available interventions.

The significance claimant attaches to this testimony is not completely clear. If claimant is arguing that the medical community has accepted RDI as an appropriate intervention, the examples he has chosen are not adequate to support such a general conclusion. If claimant is arguing that his physician, the American Speech-Language-Hearing Association, the California Board of Behavioral Sciences, and the developer of AutismPro have found RDI to be an effective intervention, his argument is speculative. The evidence does not establish that any of these persons or organizations has found RDI to be effective.

11. Neither Alexandra K. nor Jan S. claims to be an expert in autism. While they may have patients who are autistic, their practices do not include the diagnosis or treatment of autism. Alexandra K. testified that autism is a very difficult diagnosis to make even among physician-parents, and that she herself did not suspect that her son was autistic. Both Alexandra K. and Jan S., however, believe that RDI has been beneficial to their son and to them.

Alexandra K. has observed numerous instances of progress in her son’s social communication since she attended the RDI conference and applied the training she learned at the conference. In January, Alexandra K. told her son that it was cold outside and that he would need a coat. He got his coat, and brought his mother her coat, too. Over the Christmas holidays, claimant expressed emotional loss after his guinea pigs died, something that he would not have done a few years ago. Alexandra K. has found that her son is “more

included” in activities of daily living. He now helps with fewer prompts, and has found that he can ask for help from others. Alexandra K. also noticed that, when they were watching television together, her son looked at her to see if she was laughing. She believes that he wanted to share enjoyment, and that it was a step in addressing his core problems. Alexandra K. believes that claimant’s improvement is due to RDI.

Jan S. testified that the RDI conference was remarkably well-organized, and that its content was rich and succinct. It gave him a greater understanding of what autism involves, and diminished his levels of frustration. He feels that he has been able to adjust how he communicates with his son. Jan S. also uses the principles he learned at the conference when he sees patients in his office.

12. Cheryl Fletcher is one of approximately 100 certified RDI consultants in the United States. She became interested in RDI through her work as a licensed speech pathologist. (Fletcher also holds a master’s degree in speech and hearing.) Fletcher has 20 RDI clients. As a consultant, she trains the parents of the autistic child on their lifestyle and their interaction style. She guides parents by reviewing videotape of their child; only occasionally does she work directly with the child. Fletcher testified that all of her RDI clients have made progress; several have done extremely well and are close to passing out of the autism spectrum, based on ADOS. Fletcher has met claimant, and she believes that RDI is appropriate for him.

LEGAL CONCLUSIONS

1. Under the Lanterman Act, “the State of California accepts a responsibility for persons with developmental disabilities and an obligation to them which it must discharge.” (Welf. & Inst. Code, § 4501.) To achieve the objectives in a consumer’s IPP, a regional center must secure “services and supports” for the consumer that are directed toward alleviating his developmental disability. (Welf. & Inst. Code, § 4648, subd. (a).) The regional center’s obligation to secure services and supports, however, is not absolute. The question of which services and supports are necessary is determined by the IPP team, which must weigh three competing goals: the service must be “effective in meeting the goals stated in the [IPP], reflect the preferences and choices of the consumer, and reflect the cost-effective use of public resources.” (Welf. & Inst. Code, § 4646, subd. (a); see also Welf. & Inst. Code, § 4512, subd. (b).) Regional centers are under a general obligation to show that the services and supports they approve are effective. (Welf. & Inst. Code, § 4501.)

2. In light of these principles, it is within NBRC’s authority to adopt a policy that prohibits funding of unproven or experimental services and supports. The question is whether NBRC applied its policy correctly when it refused to reimburse claimant’s parents for their costs of attending the RDI conference. Claimant bears the burden of proving that RDI is not unproven or experimental.

Claimant is correct that, by demanding randomized, controlled trials to prove the efficacy of RDI, NBRC has set the bar too high. NBRC seems to recognize as much, as it acknowledges that it funds certain services for autism that are not supported by randomized,

controlled trials. But, regardless of the strength of NBRC's position, it remains claimant's burden to show that RDI is not unproven or experimental.

Claimant has failed to meet his burden. RDI is not proven. The only study of RDI, the chart review performed by Dr. Gutstein and described in his manuscript, is significantly flawed. It is acknowledged that Dr. Gutstein and Ms. Fletcher believe that RDI is effective, but their opinions are based on their anecdotal experiences and neither medical professional can offer an independent opinion on RDI: Dr. Gutstein is the developer of RDI, and Ms. Fletcher is an RDI certified consultant. It is also acknowledged that claimant's parents have observed positive changes in claimant since November 2006. Their observations are not disputed and the credibility of claimant's parents is not questioned. Despite their medical background, however, claimant's parents are not experts in autism, and they do not claim to be. Alexandra K.'s belief that claimant's progress since November 2006 is due to RDI is, in essence, a lay opinion; and, as the opinion of claimant's mother, who is rightly determined to remediate her son's core deficits, her opinion is biased in the legal – not the pejorative – sense of the word. Alexandra K.'s opinion is not sufficient to establish that claimant's recent improvement is due to RDI, as opposed to the other interventions claimant has been receiving, or to a continuation of the gradual improvement in social and communication skills that has been noted in claimant's IPPs. It is hoped that further research will establish the efficacy of RDI. At this time, however, RDI remains unproven and experimental. Under its purchase of service policy, therefore, NBRC is not obligated to use public funds to pay for it.

3. NBRC argues that, even if RDI were proven, it is prohibited from reimbursing claimant's parents because they attended the RDI conference before their appeal was heard and decided. NBRC cites California Code of Regulations, title 17, section 50612, in support of its argument. Because this decision denies claimant's appeal, it does not reach the issue of retroactivity under section 50612.

ORDER

Claimant's appeal from NBRC's decision denying reimbursement of the costs incurred by claimant's parents to attend the November 2006 RDI conference in Los Angeles is denied.

DATED: _____

DAVID L. BENJAMIN
Administrative Law Judge
Office of Administrative Hearings

NOTICE

This is a final administrative adjudication decision. Both parties are bound by this decision. Either party may appeal this decision to a court of competent jurisdiction within ninety (90) days.